ISRCTN64066164 https://doi.org/10.1186/ISRCTN64066164

The impact of a positive psychology intervention on quality of life for women with polycystic ovary syndrome (PCOS)

Submission date
03/10/2013

Recruitment status
No longer recruiting

Registration date
06/12/2013

Overall study status
Completed

Last Edited
17/06/2019

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Polycystic Ovary Syndrome (PCOS) is the most common endocrine disorder amongst women of reproductive age, affecting about 6.5% of women. PCOS is also the most prevalent cause of infertility. Women with PCOS are at an increased risk of miscarriage, cardiovascular disease, type 2 diabetes mellitus and cancer. Symptoms can include hirsutism (excessive hair growth), insulin resistance, infertility and obesity. Studies have shown that PCOS sufferers have higher levels of psychological distress than healthy individuals, including anxiety and depression. Studies show that PCOS can lead to lower quality of life and that women with PCOS are at an increased risk of suffering from a psychiatric disorder, including depression. Positive psychology interventions have been shown to help improve depressive symptoms in participants. Research has found that the positive psychology activity Three Good Things (whereby participants were asked to write down three things that went well each day and their causes) increased happiness and decreased depressive symptoms for six months. This study aims to assess the effectiveness of an online positive psychology intervention on improving the quality of life of women with PCOS.

Who can participate?
Patients aged 18 or over who have been diagnosed with PCOS by a clinician, live in the UK and have access to the internet.

What does the study involve?
Participants are randomly allocated to the intervention or the control group. The participants in the intervention group are invited to take part in a 4 week online positive psychology intervention. The positive psychology exercise is "Three Good Things". For this exercise participants are asked to write down three good things which have happened to them on each day of the intervention. They are directed to a website which enables them to fill in their three good things each day. Participants in the control group are asked to go about their usual routine and are offered the intervention after the follow-up period (6 weeks).

What are the possible benefits and risks of participating?
The positive psychology intervention, "Three Good Things", has been shown to increase

happiness and decrease depressive symptoms. There are no known risks to participating in this study.

Where is the study run from?
The lead study centre is the University of Derby. The trial is being run in association with a PCOS clinic at the Royal Derby Hospital (UK)

When is the study starting and how long is it expected to run for?
January 2014 to November 2015

Who is funding the study?
University of Derby (UK)

Who is the main contact?
Sophie Williams
s.williams3@derby.ac.uk

Contact information

Type(s)
Scientific

Contact name
Miss Sophie Williams

Contact details
University of Derby
Kedleston Road
Derby
United Kingdom
DE22 1GB
-
s.williams3@derby.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised controlled trial to investigate whether an online psychology intervention can improve the quality of life of women with polycystic ovary syndrome (PCOS)

Study objectives
Women with Polycystic Ovary Syndrome (PCOS) can experience a low quality of life: a non-invasive clinical trial offering an online positive psychology intervention to women with PCOS may, therefore, be beneficial. We propose to carry out a fully randomised clinical trial into the benefits of an online positive psychology intervention for Derby-based women with PCOS over a four week period, using quality of life as an endpoint. This will be the first study to investigate whether an online intervention can improve the quality of life of women with PCOS.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. University of Derby Psychology Research Ethics Committee (PREC), 21/08/2013, ref: 087-13-SW
2. NRES Committee East Midlands Nottingham 2, 14/11/2013, REC ref: 13/EM/0393

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Polycystic Ovary Syndrome (PCOS)

Interventions
Randomisation shall be stratified in order to ensure an equal distribution in length of diagnosis of PCOS. Pragmatic randomisation may be used if a participant has a strong preference to be in a particular group (either control or intervention).

All participants in the control group will be offered the intervention after the follow-up period. Intervention group: Four week online positive psychology intervention - "Three Good Things" activity.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Quality of life, measured using the PCOS QoL (in development) at at baseline, 4 and 6 weeks

Secondary outcome measures
Anxiety and depression, measured using the Hospital Anxiety and Depression Scale (HADS) at baseline, 4 and 6 weeks

Overall study start date
01/01/2014

Completion date
01/11/2015

Eligibility

Key inclusion criteria
1. Aged 18 or over
2. Diagnosed with Polycystic Ovary Syndrome by a clinician
3. Lives in the UK
4. Has access to the internet

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
200

Key exclusion criteria
1. Participants with mental incapacity unable to give informed consent
2. Participants unable to understand verbal and written information in English (as the study is an online study and so translation for individuals not able to understand English is not possible)

Date of first enrolment
12/01/2015

Date of final enrolment
17/04/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Derby
Derby
United Kingdom
DE22 1GB

Sponsor information

Organisation
University of Derby (UK)

Sponsor details
c/o Chris Bussell
Head of Science
Kedleston Road
Derby
England
United Kingdom
DE22 1GB

Sponsor type
University/education

ROR
https://ror.org/02yhrrk59

Funder(s)

Funder type
University/education

Funder Name
University of Derby

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication of a ‘lessons learned paper’ in a journal within the next year.

2016 results published in thesis https://derby.openrepository.com/handle/10545/620535

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No